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Physician Views – Sanofi's no-go decision on lixisenatide monotherapy sharpens focus on GLP-1/insulin combination products – what are the expectations of GPs, endocrinologists based in the US, 5EU?

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Abstracts

A key dynamic of the highly competitive diabetes market is the relatively limited differentiation between products positioned in each of the main drug classes. Furthermore, current late-stage pipelines are characterised by incremental advantages over available therapies rather than novel approaches.

It is of little surprise then that fixed-dose combinations – such as GLP-1 agonists and longer-acting insulins – are being developed by a number of the leading diabetes players.

Adding GLP-1 analogues to insulin has a number of obvious benefits, due to the lower hypoglycaemia risk and weight control advantages that this drug class confers. Key opinion leaders (KOLs) recently interviewed by FirstWord's Therapy Trends team were enthusiastic about this approach, albeit if they did express concern over the ability of manufacturers to combine once-daily dosing of a GLP-1 agonist with more flexible dosing for the insulin component, which would offer the best available approach for physicians.

The race to gain first-to-market advantage took another turn last week when Sanofi announced that it will delay the US filing for its GLP-1 agonist lixisenatide as it awaits the maturation of data from an ongoing cardiovascular outcomes study. This also suggests that development of a combination Lantus/lixisenatide product is now taking precedent over lixisenatide as a monotherapy, with Phase III studies due to begin in

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2014 - see ViewPoints: Sanofi diabetes portfolio becomes even more Lantus-centric in light of lixisenatide delay; KOLs question dosing of a combination Lantus/lixisenatide product, but commercial opportunity significant.

Sanofi has previously demonstrated a willingness to shift its development strategy for the Lantus/lixisenatide combination in order to maximise the associated commercial opportunity. In light of the FDA's decision to reject Novo Nordisk's Tresiba in February, Sanofi announced that it would prioritise a fixed-ratio combination due to technical difficulties with its proposed Fix-Flex device, citing that its approach would focus on time-to-market to maximise the opportunity provided by Novo Nordisk's setback (the Danish company is developing its own combination product – IDegLira – comprising Tresiba and the market leading GLP-1 agonist Victoza).

With the GLP-1 agonist market not only dominated by Victoza but set to become increasingly crowded over the next few years, analysts have frequently suggested that the biggest commercial opportunity for lixisenatide sits within a combination; particularly given the dominance of Lantus in the long-acting insulin market.

This week's Physician Views poll will ask endocrinologists and general practioners based in the US and 5EU (France, Germany, Italy, Spain and the UK):

What percentage of patients receiving GLP-1 agonist therapy are also prescribed an insulin?

To what percentage of patients, physicians would expect to prescribe a fixed-dose combination GLP-1 agonist/insulin product?

To what type of patients this combination would be most frequently prescribed to?

How advantageous a flexible-dose combination would be versus a fixed-dose combination?

To what percentage of Lantus patients they would anticipate switching to a Lantus/lixisenatide combination within a year of launch?

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